ergoline

ergoscan

Ambulatory Bloodpressure System

ergoscan duo

ABP with Spo2 recording

User manual

201000098000 • version 2013-09 • english

Manual

This manual was written with the utmost care. Should you still find details that do not correspond with the system, please let us know and we will correct the issue as soon as possible.

We reserve the right to modify the design and technical features of the device and are not bound by the information and illustrations provided in this manual.

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CE 0123

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EG-KONFORMITÄTSERKLÄRUNG / DECLARATION OF CONFORMITY

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Wir / We	**ergoline GmbH** **Lindenstr. 5** **72475 Bitz (Germany)**
erklären in alleiniger Verantwortung,dass das Medizinprodukt / declare on our own responsibility that the medical device	**ergoscan**
Modelle / Models	**121.002 ergoscan PC-System** **121.003 ergoscan Zusatzrekorder** 121.002 ergoscan PC-System 121.003 ergoscan Additional recorder
und das Zubehör / and the accessories	**701.201 Blutdruck-Manschette, Standard** **701.202 Blutdruck-Manschette, Groß** **701.203 Blutdruck-Manschette, Kinder** 701.204 Blood pressure cuff, standard 701.205 Blood pressure cuff, large 701.206 Blood pressure cuff, children
mit den Anforderungen der Richtlinie übereinstimmt / is in conformity with the Directive	**93/42/EWG und 2007/47/EG** 93/42/EEC and 2007/47/EC
Klasse / class	**IIa**
UMDNS-Code / UMDNS-Code	**12386**
Benannte Stelle / Notified Body:	**TÜV SÜD Product Service GmbH** **Ridlerstr. 65** **80339 München** **Germany**
Konformitätsbewertungsverfahren / Conformity assessment procedure:	**Anhang I /** appendix I
Klassifizierung nach / Classification according to:	**Anhang IX /** appendix IX

Beginn der Gültigkeit / Begin of the validity:
Datum/Date: 30.03.2007

Ort/City:
Bitz den, 14.05.2010

Axel Bodmer

ergoline

EG-KONFORMITÄTSERKLÄRUNG / DECLARATION OF CONFORMITY

CE 0123

Wir / We	**ergoline GmbH** **Lindenstr. 5** **72475 Bitz (Germany)**
erklären in alleiniger Verantwortung,dass das Medizinprodukt / declare on our own responsibility that the medical device	**ergoscan duo**
Modelle / Models	**121.301 ergoscan duo PC-System** **121.302 ergoscan Zusatzrekorder** 121.301 ergoscan duo PC-System 121.302 ergoscan duo Additional recorder
und das Zubehör / and the accessories	**701.201 Blutdruck-Manschette, Standard** **701.202 Blutdruck-Manschette, Groß** **701.203 Blutdruck-Manschette, Kinder** **701.217 SpO2 Sensor SoftTip 1,80m** 701.204 Blood pressure cuff, standard 701.205 Blood pressure cuff, large 701.206 Blood pressure cuff, children 701.217 SpO2 Sensor SoftTip 1,80m
mit den Anforderungen der Richtlinie übereinstimmt / is in conformity with the Directive	**93/42/EWG und 2007/47/EG** 93/42/EEC and 2007/47/EC
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Beginn der Gültigkeit / Begin of the validity:
Datum/Date: 14.05.2010

Ort/City:
Bitz den, 14.05.2010

Axel Bodmer

General Information

- The product ergoscan carries the CE mark CE-0123 in accordance with European Council Directive 93/42/EEC in relation to medical devices and complies with the fundamental requirements stated in Appendix I of this Directive. The device has an internal power source and comes within Class IIa (MDD)..

- The device has an application part of the type BF (defribrillator protected).

- Standard EN 60601-1 ‚Medical electrical equipment, Part 1: General Requirements for Safety' is complied with, as well as the immunity requirements of standard EN 60601-1-2 ‚Electromagnetic Compatibility - Medical Electrical Equipment'..
  The device is interference-free in accordance with EN 55011 - Class B.

- The symbol means:

  Consult accompanying documents.
  It indicates points which are of particular importance in the operation of the device.

- This manual forms part of the device. It should always be kept near to the device. Correctly observing the manual ensures that the device will be used in an appropriate manner and for the purpose it is intended. It will also ensure the health and safety of users and patients dependent on it..

- Observance of the safety information protects from injuries and prevents inappropriate use of the device. All equipment users and persons responsible for assembly, maintenance, inspection and repair of the device must read and understand the content of this manual, before using or work on it.
  Paragraphs with special symbols are of particular importance.

- Please read through the whole manual carefully, since information that is relevant to several sections is only provided once.

- The printed text of this manual is in accordance with the version of the device, as well as the relevant safety instructions standards, at the time that this manual was printed.
  All industrial property rights are reserved in relation to any devices, circuits, processes, software programs and names described in this manual.

- The ERGOLINE quality management system complies with the standards ISO 9001: 2000 and EN ISO 13485: 2003.

- The safety information given in this manual is classified as follows:

Danger

indicates an imminent hazard. If not avoided, the hazard will result in death or serious injury.

Warning

indicates a hazard. If not avoided, the hazard may result in minor injury and/or product/ property damage.

Caution

indicates a potential hazard. If not avoided, the hazard may result in minor injury and/or product/property damage.

- To ensure patient safety, the specified measuring accuracy, and interference-free operation, we recommend using only original ERGOLINE accessories. The user is responsible if non-ERGOLINE accessories are used.

- ERGOLINE is responsible for the safety, reliability, and performance of the equipment, only if

  - modifications and repair are carried out by ergoline GmbH or by an organization expressly authorized by ergoline GmbH
  - the equipment is used in accordance with the instructions given in this operator's manual.

Intended Use

Ergoscan and ergoscan duo are manually-operated blood pressure measuring devices, carried by the patient for long-term measurement of non-invasive blood pressure and for the recording of oxygen saturation values (ergoscan duo only). They can be used for adults, children and infants by applying the corresponding cuffs and sensors. Ergoscan must not be used for newborn babies and is not suitable for use in Intensive Care Units.
Ergoscan can be used to take blood pressure measurements at various intervals for up to 30 hours and is able to store the measurement results
Ergoscan duo additionally allows the recording of SpO2 values in programmable sampling intervals.

Biocompatibility

The parts of the product described in this manual, including all accessories that come in contact with the patient during the intended use, fulfill the biocompatibility requirements of the applicable standards if applied as intended.

If you have questions in this matter, please contact ERGOLINE or a representative.

Applicable Laws, Regulations and Directives

- 93/42/EEC (Medical Device Directive of the EU)

- 89/336/EEC (Electromagnetic Compatibility Directive of the EU)

- EN 1060-1 Non-invasive sphygmomanometers, Part 1: General requirements

- EN 1060-3 Non-invasive sphygmomanometers, Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems

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Safety Information

Danger

• Explosion Hazard •

The device is not designed for use in areas where an explosion hazard may occur.
Explosion hazards may result from the use of flammable anesthetics, skin cleansing agents or disinfectants.

Warning

• Patient Hazard, Equipment Damage •

The device should only be used together, or in combination with components of other equipment, when you have ensured that this connection does not adversely affect the health and safety of patients and users, or the environment.

If the information provided with the device is not clear on how to make a safe connection that will ensure the health and safety of patients, users, as well as the environment, then please contact the manufacturer or consult a technical expert. At all times, observe standard IEC 60601-1-1.

· *The ergoscan Recorder can be connected to, and operated from, a PC on which ErgoScanWin software has been installed. Please note that no patient should be connected to the ergoscan recorder as long as it is connected to the PC.*

Before using the device on a patient, the user should check that the device functions safely and as intended.

Warning

• Patient Hazard, Equipment Damage •

Users must be familiar with how to operate the device.

Medico-technical devices should only be used by suitably-qualified or experienced persons, who can ensure that the device is used correctly.

The device does not contain any components that need to be replaced by users. Never open the casing of the device (please contact the Service Department)

INSTALLATION

PC-SOFTWARE

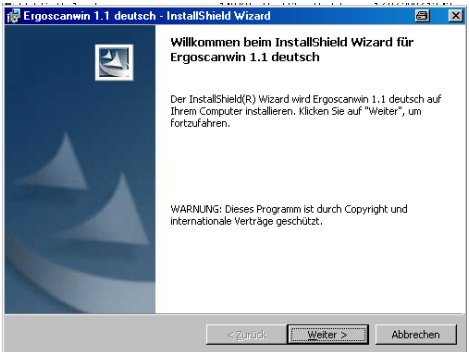
- Insert the Ergoscan CD into the CD-ROM drive

- The installation starts automatically, if the „autostart function" of the CD drive is activated. If not:
  - start the Windows-Explorer
  - select the CD drive
  - doubleclick on **start.exe**

- Select the installation language.
  (The program language can later be changed under „Settings"):

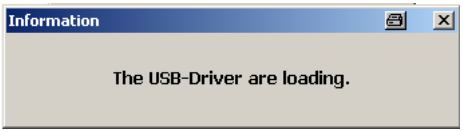
- The installation starts.

INSTALLATION LANGUAGE SELECT MENU


Ergoscanwin 1.1 deutsch - InstallShield Wizard
Willkommen beim InstallShield Wizard für Ergoscanwin 1.1 deutsch
Der InstallShield(R) Wizard wird Ergoscanwin 1.1 deutsch auf Ihrem Computer installieren. Klicken Sie auf "Weiter", um fortzufahren.
WARNUNG: Dieses Programm ist durch Copyright und internationale Verträge geschützt.
< Zurück
Weiter >
Abbrechen

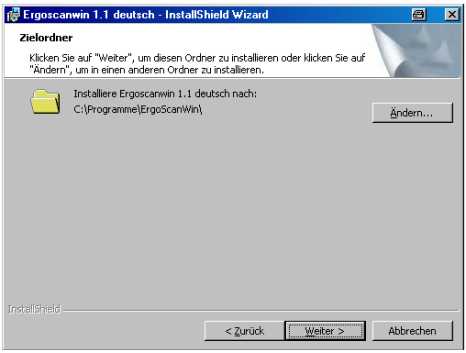
SOFTWARE INSTALLATION

- First, the installation of the USB driver (virtual COM port) is launched -please confirm the license agreement and follow the hints given on screen.



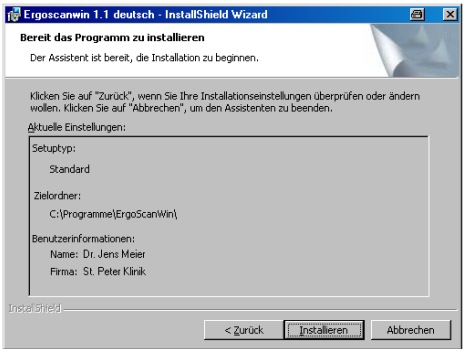
USB DRIVER INSTALLATION

- C:\Program Files\ErgoscanWin is used as the default installation folder.
  By using [Browse] it is possible to change the installation path.


Ergoscanwin 1.1 deutsch - InstallShield Wizard
Zielordner
Klicken Sie auf "Weiter", um diesen Ordner zu installieren oder klicken Sie auf "Ändern", um in einen anderen Ordner zu installieren.
Installiere Ergoscanwin 1.1 deutsch nach:
C:\Programme\ErgoScanWin\
Ändern...
InstallShield
< Zurück
Weiter >
Abbrechen

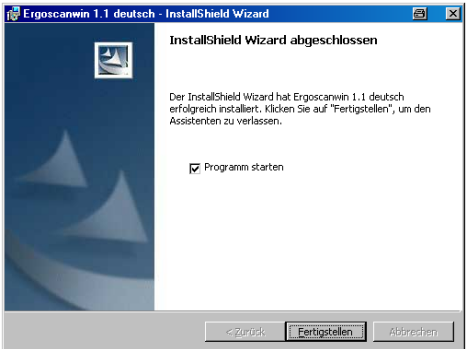
FOLDER FOR PORGRAM INSTALLATION

- Before the installation finally starts, all parameters are displayed on screen.
  Confirm by [Install] to start the process.



SUMMARY FOR INSTALLATION

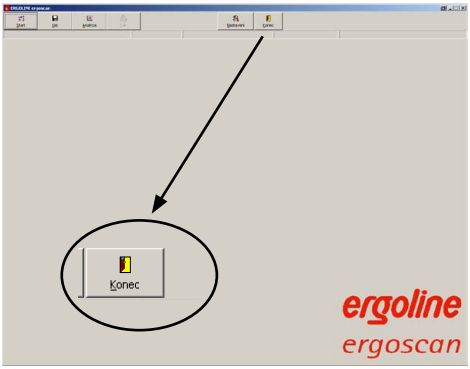
- After the installation is completed, the ergoscan program is started and all needed settings can be configured.


Ergoscanwin 1.1 deutsch - InstallShield Wizard
InstallShield Wizard abgeschlossen
Der InstallShield Wizard hat Ergoscanwin 1.1 deutsch erfolgreich installiert. Klicken Sie auf "Fertigstellen", um den Assistenten zu verlassen.
Programm starten
< Zurück
Fertigstellen
Abbrechen

INSTALLATION COMPLETE AND PROGRAM START

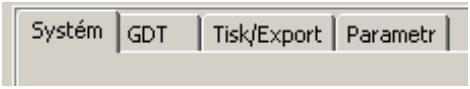
Settings

After starting the program the main screen appears. Click on „Settings“ to configure the software.



Main Screen with Button Settings

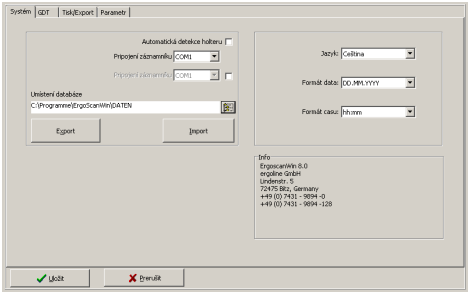
The different settings are split onto 4 tabs *[System], [GDT], [Print / Export] and [Parameter].*



Tabs for different Settings

System Settings

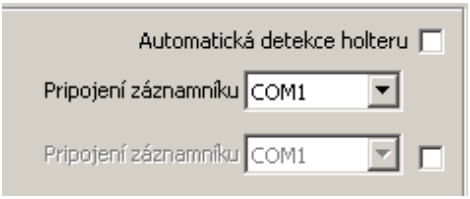
All settings for the standard use of the ergoscan-system are performed on this tab.



Settings System

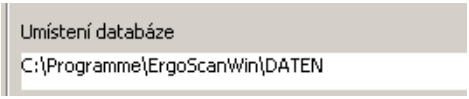
- It is recommended to activate the automatical identification of the recorder connection.

  In case of technical problems or if different recorders are used, it is possible to fix the used COM ports.



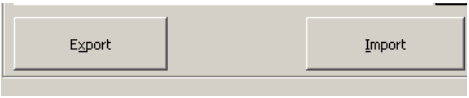
Recorder Connection

- The folder for the ergoscan database may be changed (see also *Network Installation*).



FOLDER/PATH FOR DATABASE

- [EXPORT] stores the complete ergoscan database to a special backup folder.
  By using [IMPORT] the database is restored.



BACKUP OF DATABASE

Caution

• Data loss •

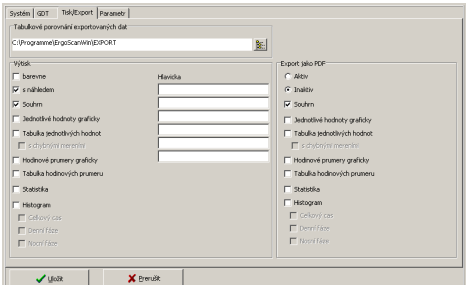
IMPORT of a stored database will OVERWRITE the actual database !

- Select program language and date/time format.

LANGUAGE, DATE- /TIME FORMAT

Settings Print/Export

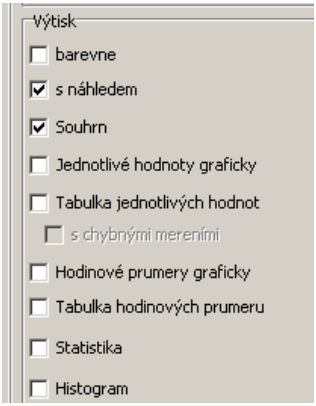
On this tab all settings for printing and data export are set.



Settings Print / Export

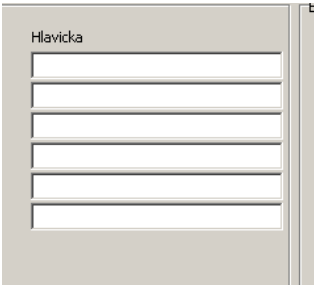
Print

- Selecting standard print pages., print preview and coloured printout (e.g.. for ink jet printers).



Configuration of printout

- Headings that should be included with every print-out page..



Header for print pages

EXPORT

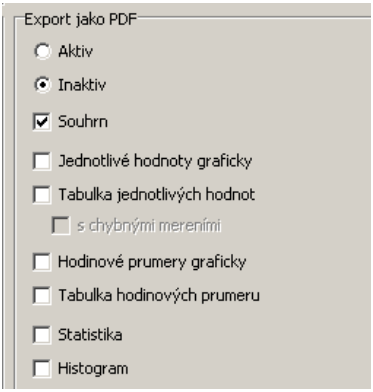
The ergoscan program can store the printout pages as a PDF file and export the measurement values in a file (CSV format).for later analysis (e.g. Excel).
The filename contains all necessary informations::

P^<type>_<workstation>^<slot#>_<id>^<last>^<first>_<StartTime>_<exportTime> **. PDF / .TXT**

^	=	block separator
<type>	=	"REPORT" for printout
<workstation>	=	workstation name
<slot#>	=	1 (slot number of workstation)
<id>	=	patient-ID
<last>	=	last name
<first>	=	first name
<StartTime>	=	starttime of ergoscan recording in format YYYYMMDDHHMMSS
<exportTime>	=	time of PDF export in format YYYYMMDDHHMMSS

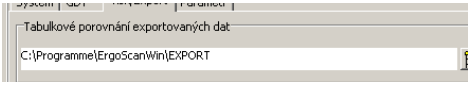
e.g..: P^REPORT_Comp^1_12345^Smith^Peter_20031216104632_20040318153145.pdf

- Activation of PDF export and selection of standard pages.



SETTINGS FOR PDF EXPORT

- Select folder for PDF files and CSV files



FOLDER FOR DATA– AND PDF EXPORT

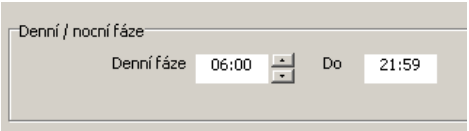
Settings Parameter

On this tab the standard values for analysis of the data are set.

It is possible to adapt these parameters individually for every evaluation.

Day-/ nightphase

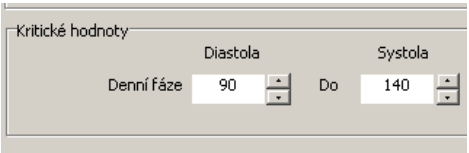
- The standard time ranges for dayphase and nightphase are set.



Time range for dayphase / nightphase

Critical values

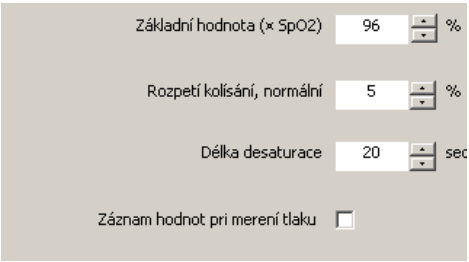
- Set critical values for day and night.
  These values will be displayed as lines in the grafic representation of the evaluation and are used for statistical calculations.



Critical values for Day-/Nightphase

Oxygen saturation / desaturation

- Set standard values for analysis of SpO2 measurements.



Analyse-Parameter SpO2
(nur für ergoscan duo)

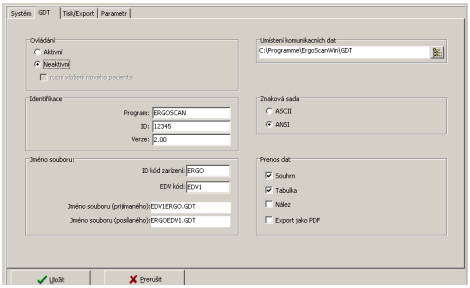
Settings GDT

The GDT interface is a standard produced by the German Quality Assurance Medical Software (QMS – ‚Qualitätsring Medizinische Software') for system-independent data transfer between medical devices and general practice IT systems.

The ErgoscanWin software has an integrated GDT interface (‚Device Data Carrier interface' – ‚Geräte-Daten-Träger') and therefore allows for easy data transfer with a general practice IT system or a hospital information system.

Please contact your IT dealer to find out what the correct settings of the GDT interface are in relation to the relevant IT system.

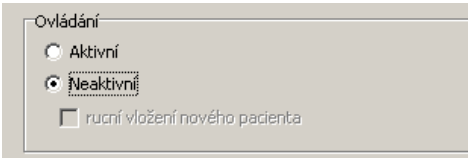
All standard settings in the GDT standard (Version 2.0) can be adjusted on an individual basis.



GDT Settings

Operation
This settings enable / disable the GDT software interface.

If activated, the software checks at start for an existing GDT file (with the defined folder/ filename) and interprets this file.
If no such file exists, a „normal" program start is performed.



Activating the GDT interface

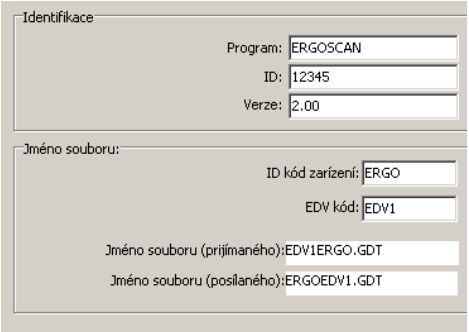
Hint

If GDT operation is activ, the manual admission of new patients should be inactiv to avoid patientname or patient-ID mismatch between ergoscan software and IT system.

Identification
This ID is an unique identification (1 to 8 characters) of the ergoscan software to be used by the IT system.

File names
The filenames for the data exchange between ergoscan software and IT system are defined in this box.
The filenames are combined by a token (1..4 characters - e.g. ERGO) for the device and another token for the IT system (e.g. EDV1).

The filenames for data transmit and receive are combinations of these tokens, the filename extensions are fixed to *. GDT.



GDT IDENTIFICATION / FILENAMES

Folder for communication files
The folder for the data transfer files can be defined. To avoid mismatch in a network environment, each workstation should use another folder.

FOLDER FOR COMMUNICATION FILES

HINT:
The GDT file written by ergoscan software has to be read and deleted by the IT system - otherwise no new GDT file can be generated by the ergoscan software.

Character set
The used characterset can be selected (ASCII or ANSII).

CHRACATERSET

Data transfer

Selct the results to be transfered to the IT system.

If the pDF export is activated, the GDT file contains a link to the simultaneously generated PDF file.

SELECTION OF DATA TO BE TRANSFERED

Example Summary (one line)

```
ABPM: Day 112/ 69/ 79 -  Night 94/ 59/ 74 = -15/-14/-7 %
```

Example Table

24 h ABPM	Dayphase 06:00-21:59	Nightphase 22:00-05:59	Difference Day / nightphase
Average:			
Ps[mmHg]	112	94	-15.4%
Pd[mmHg]	69	59	-14.4%
HR[P/min]	79	74	- 6.8%

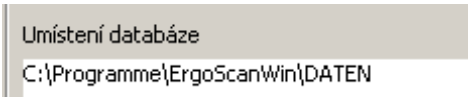
Network installation

The ErgoscanWin-Software may be installed in a computer network, e.g. patient data and evaluations can be stored on a server and accessed by all connected workstations.

Define a database folder on the server and enable access for all workstations.

The perform a local software installation on all workstations used for ergoscan program.

Change the database folder under [Settings] to the previously defined server folder:



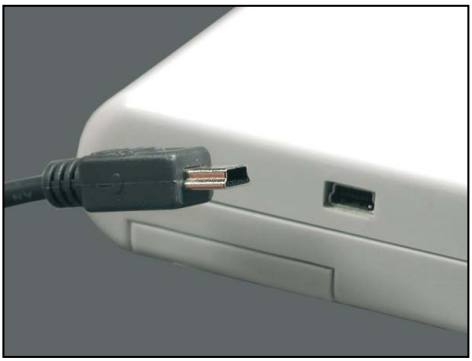
Folder / Path for database

Connecting the ergoscan recorder

TIn order to start the recorder and read information from it, the recorder must be connected to the PC via an USB cable.

This USB cable is connected to a free USB port on the computer.

The USB cable also needs to be plugged into the mini USB port, which is located at the back of the casing of the device. Please ensure that the plug is in the right position when connecting it:



Connecting the mini usb cable

ERGOSCAN RECORDER

OPERATION CONTROLS

1 Cuff connector

2 LC display to display all relevant information

3 Day/Night button to change the measurement interval between day and night interval

4 Info button to display the most recently measured values. The following values will be displayed respectively:
- Systolic value ‚S/mmHg'
- Diastolic value ‚D/mmHg'
- Pulse frequency ‚HR/min-1'.

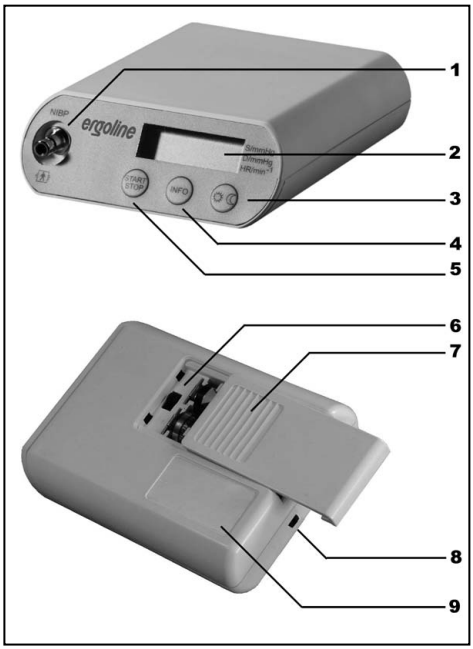
5 Start/Stop button to initiate additional measurements and to interrupt a measurement in process.

6 On- / Off-Switch

7 Battery compartement lid

8 Connecting port for PC connecting cable

9 Label with serial number etc.



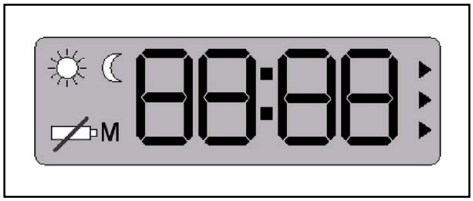
OPERATION CONTROLS

LCD DISPLAY WITH ALL SYMBOLS AND DISPLAY OPTIONS

M

Flashes for every detected oscillation
Displayed constantly when measurement data has been stored

Flashes when batteries are running out
Continuous display when batteries are empty and no measurements can be made



LC-DISPLAY OF ERGOSCAN RECORDER

Day phase selected

Night phase selected

TIME DISPLAY

The integrated clock is automatically set to the actual PC system time whenever the recorder is started with a new patient.

No manual setting of the integrated clock possible.

Power supply

The Ergoscan Recorder requires either two nickel metal hydride rechargeable batteries.
The use of alkaline batteries is not recommended.

When starting the recorder via the ErgoscanWin software, please ensure that the relevant power source has been selected.
In addition, the device also has a built-in lithium cell to indicate the time.
The capacity of two fully-charged rechargeable batteries or two new batteries ensures at least 30 hours of operation or 200 measurements

.

Hint

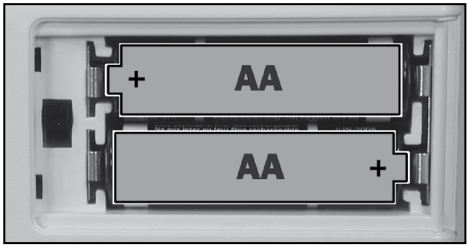
- *Battery capacity reduces in line with increased use. If the capacity of the two fully-charged rechargeable batteries clearly falls below 24 operating hours, then you need to replace them.*
- *Always insert two fully-charged rechargeable batteries, before taking a new measurement.*

Inserting Batteries

The battery compartment is located on the underside of the recorder.
In order to open this compartment, use your thumb to move the battery compartment lid approx. 6 mm backwards and then remove the lid in an upward direction:

Open the battery compartment

Please ensure that the batteries are inserted correctly!!



CAUTION: Polarity

Function control

The PhysioQuant recorder will automatically carry out a self-test when it is switched on, which will activate all symbols and segments of the LCD display.
The device will then check the inserted (rechargeable) batteries and will display the available capacity.
In this context, e.g. ‚C100' refers to a 100% (rechargeable) battery capacity (fully charged) and ‚C50' refers to a 50% (rechargeable) battery capacity (half empty).

In order to carry out a 24 hour measurement, the capacity needs to be at least 90%.
If the capacity is below 90%, then you will need to insert new batteries or fully-charged rechargeable batteries.
When the self-test has been completed successfully, the following information will appear on the display after the power supply test:

- The actual time
- The measurement phase (day/night)
- Whether any measurement data has been stored („M" displayed)

Connecting the Cuff to the Recorder

To connect the blood pressure cuff to the recorder, plug the metal connection of the cuff as far as possible into the connection point at the recorder, until it clearly clicks into place.

The cuff can be removed again from the recorder by pulling back the external metal plug cover

Ergoscan Cuffs

Various cuff sizes are available for the Ergoscan recorder (standard, large and children size).

Please select the correct cuff size (see printed text on the cuff)

Cleaning and desinfection of the cuffs are described in the chapter „Cleaning and Maintanance".

Caution

• Wrong measurement •

Cuffs that are too small will result in measurements that are too high. Cuffs that are too large will result in measurements that are too low.

Replace the cuffs at regular intervals. Damaged Velcro fasteners may lead to incorrect measurements.

Ergoscan Duo recorder

Operation controls

1 SpO2 sensor connector

2 Cuff connector

3 Start/Stop button to initiate additional measurements and to interrupt a measurement in process.

4 LC display to display all relevant information

5 Combined Day/Night and Info-Button:

Day/Night button to change the measurement interval between day and night interval

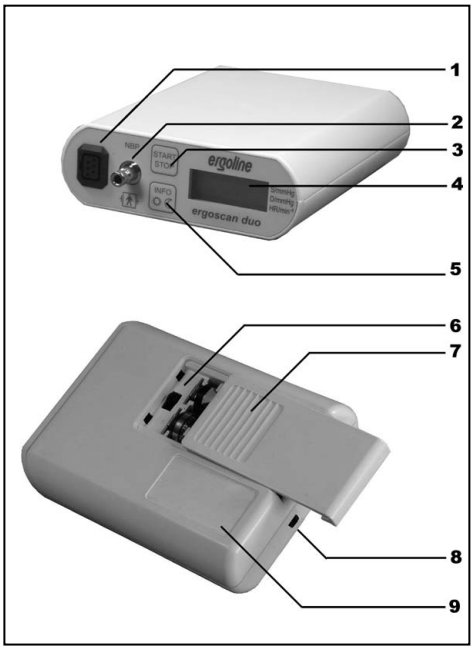
Info button to display the most recently measured values. The following values will be displayed respectively:
- Systolic value S/mmHg'
- Diastolic value D/mmHg'
- Pulse frequency HR/min-1'.

6 On- / Off-Switch

7 Battery compartement lid

8 Connecting port for PC connecting cable (USB)

9 Label with serial number etc.

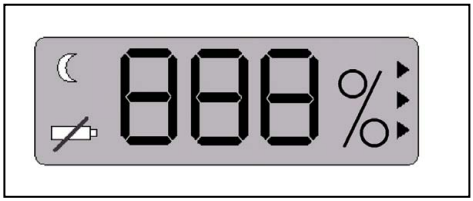


Operation controls

LCD DISPLAY WITH ALL SYMBOLS AND DISPLAY OPTIONS

The LC display of the ergoscan duo recorder shows all measurement results and important informations.

Flashes when batteries are running out.
Continuous display when batteries are empty and no measurements can be made



LC-DISPLAY OF ERGOSCAN DUO RECORDER

Night phase selected

RECORDER TIME

The integrated clock is automatically set to the actual PC system time whenever the recorder is started with a new patient.

No manual setting of the integrated clock possible.

Power supply

The Ergoscan duo Recorder requires two nickel metal hydride rechargeable batteries - it is not possible to use batteries.

In addition, the device also has a built-in lithium cell to indicate the time.

.

Hint

- *Battery capacity reduces in line with increased use. If the capacity of the two fully-charged rechargeable batteries clearly falls below 24 operating hours, then you need to replace them.*
- *Always insert two fully-charged rechargeable batteries , before taking a new measurement.*

Inserting Batteries

The battery compartment is located on the underside of the recorder.
In order to open this compartment, use your thumb to move the battery compartment lid approx. 6 mm backwards and then remove the lid in an upward direction:

Open the battery compartment

Please ensure that the batteries are inserted correctly!!

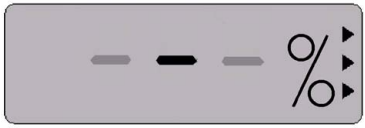
CAUTION: Polarity

Function control

The Ergoscan duo recorder will automatically carry out a self-test when it is switched on, which will activate all symbols and segments of the LCD display.
The actual version of the recorder software is displayed (e.g. „P10" for software version 1.0).
The device will then check the inserted rechargeable batteries and will display the available capacity in percent (e.g. 100% fully charged / 50% half empty).

In order to carry out a 24 hour measurement, the capacity needs to be at least 90%.
If the capacity is below 90%, then you will need to insert fully-charged rechargeable batteries.

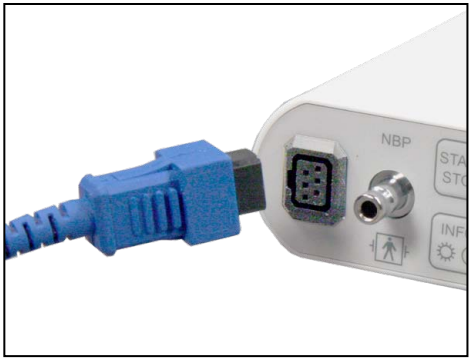
The recorder is now in standby and the display shows a running line with the percent symbol.



Standby Display

Connecting the SpO2-Sensor to the Recorder

Plug the connector of the SpO2 Softip sensor into the appropriate jack of the recorder.

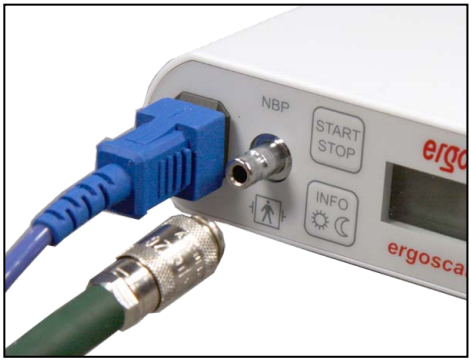


Connecting the SpO2 sensor

Connecting the cuff to the Recorder

To connect the blood pressure cuff to the recorder, plug the metal connection of the cuff as far as possible into the connection point at the recorder, until it clearly clicks into place.

The cuff can be removed again from the recorder by pulling back the external metal plug cover



Connecting the cuff

Ergoscan Cuffs

Various cuff sizes are available for the Ergoscan recorder (standard, large and children size).

Please select the correct cuff size (see printed text on the cuff)

Cleaning and desinfection of the cuffs are described in the chapter „Cleaning and Maintanance".

Caution

• Wrong measurement •

Cuffs that are too small will result in measurements that are too high. Cuffs that are too large will result in measurements that are too low.

Replace the cuffs at regular intervals. Damaged Velcro fasteners may lead to incorrect measurements.

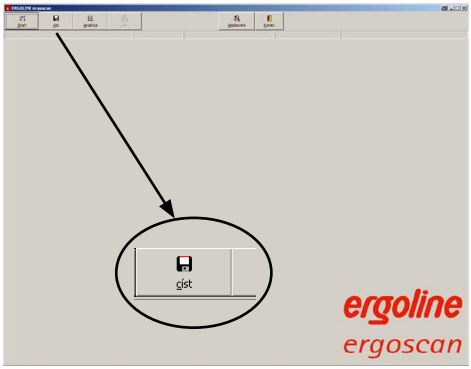
Initiate 24h BP measurement

Connecting the recorder

- Connect the Ergoscan Recorder to the PC and switch on the recorder.
  The on/off switch is located beneath the lid of the battery compartment.
  Following self test and battery capacity the display shows the PC symbol:

Starting the Program

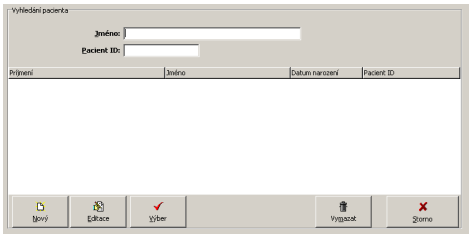
After the Ergoscan software has started, the main screen appears.
To programme the recorder, click on the ‚Start' tab to open the relevant menu:



Main screen: Start

Select a Patient

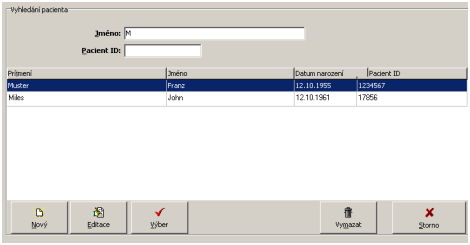
The selection window of the patient database appears:



Selection window Patient

In the ‚NAME' field, enter the first letter of the patient's surname. All patients whose names start with this letter will then be displayed (e.g. those beginning with M):.

Select the required patient, by double clicking on the relevant line

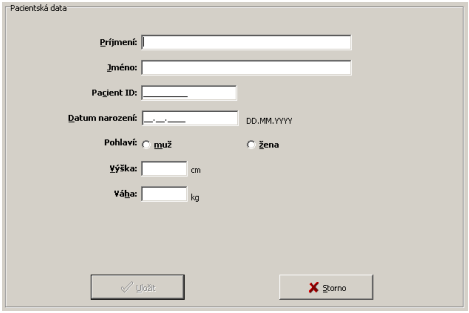


SELECT ALL PATIENTS WITH „M"

ADDING A NEW PATIENT

If the required patient is not in the database, then you can directly enter new patient data.

To do so, open the entry screen with the [NEW] button. Enter all the required data and save it to the database with [Save]:



ADDING A NEW PATIENT

EDITING PATIENT DATA

Patient data that has been entered can be edited and updated at any time ([Edit] button in the Patient selection window).

EXCEPTION: Patient ID cannot be changed once it has been entered and saved!

Programming the Recorder

After you have selected the patient, a window will appear for configuring and programming the Ergoscan Recorder.

Measurement (ergoscan duo only)
Select, if the ergoscan duo recorder should record bloodpressure only, SpO2 only or both parameters.

Number of measurement intervals
Up to 4 different measurement intervals can be selected. The standard setting is at 2 intervals (day and night phase).

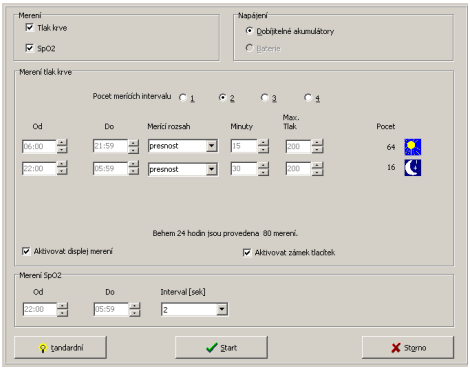
Power supply
The type (normal battery or rechargeable battery) that is used for long-term measurements is set.. Ergoscan duo needs rechargeable batteries.

Bloodpressure measurement
From ... To ...
The beginning and end of selected intervals can be set in hours.

Measurement interval
exact: measurements are taken at the exact intervals in minutes that have been set.
approx.: measurements randomly vary at approx. +/- 2 minutes around the times set.

Minutes
The interval between subsequent measurements can be programmed to range between 2 and 90 minutes.

Max. pump pressure
Limits the max. cuff pressure to the value set between 200 mmHg and 280 mmHg.



Setting Measurement Parameter

Number
The number of all programmed measurements will be displayed for each measurement interval and a summary is provided for each 24 hours..

Activate display
The results of a bloodpressure measurement are displayed on the recorder or not.

Activate keylock
The day / night button on the recorder keyboard is activ or not.

CAUTION
• **Mix-up of patients** •

The recorder has to be started by the ErgoscanWin software. If not, the new measurement is added to the former patient.

Only when a new long-term measurement is started, the recorder deletes all old patient data and measurement values.

ergoscan duo only:
Measurement SpO2
from.. to...
Start and end of SpO2 recording

Sampling intervall
The intervall between two SpO2 measurements is defined.

Standard
The [Standard] button will reset the parameters to the following values:

2 measurement intervals:

Interval 1 (day phase):
06:00 - 21:59 Exact every 15 min. 250 mmHg

Interval 2 (night phase):
22:00 - 05:59 Exact every 30 min. 250 mmHg

SpO2 measurement:
22:00 - 05:59 intervall 2 sec

After saving the selected configuration, the starting sequence of the recorder will commence by clicking on the [Start] button.

The recorder will first check whether there are any previous measurements that have not yet been read. If this is the case, then a warning will be displayed.
If this is not the case, then the recorder will be switched off and the new patient data and measurement intervals are stored in the recorder.

Attaching the cuff and recorder

Please remove the connecting cable to the PC.

Attach the cuff to the arm that is less used by the patient.
For adults: approx. 2 finger widths above the elbow.
For children: slightly closer to the elbow.
Ensure that the cuff does not rise up when the arm is being bent.

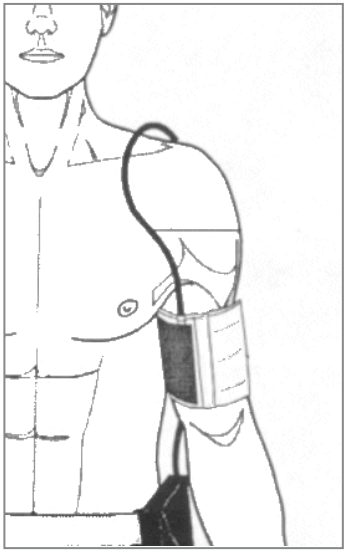
Please ensure that:
- the connecting tube points upwards to the shoulder
- the side of the cuff with ‚Patient' written on it makes contact with the skin
- the arrow lies over both the arteria brachialis and arteria femoralis
- the cuff is attached tightly and closely surrounds the tissue, but exerts no pressure on the veins.

Switch on the Ergoscan Recorder and place it in the carrier bag.

CAUTION

• Risk to patients •

The Ergoscan recorder must not be connected to the PC, while it is being attached to a patient.

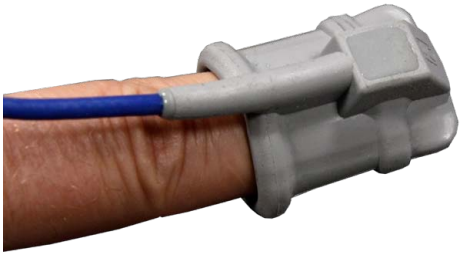


Attaching the cuff

Attaching the cuff and recorder

Place the index finger into the SoftTip sensor. The cable should run on top of the hand.

After some seconds the actual SpO2 value is displayed on the recorder display (alternating with the actual heart rate).



Attaching the Sensor

Use the belt to attach the bag to the body of the patient. For hygienic reasons, the bag should not come into direct contact with the skin.

Place the cuff tube and -with ergoscan duo- the cable of the SpO2 sensor around the patients neck in order to release any strain and connect it to the recorder.

Ensure that the tube cannot become disconnected while the measurement is being taken.

Test measurement

A test measurement must always be carried out after the cuff has been attached and the recorder connected. The automatic measurements will not start, if START/STOP has not been activated.

In order to avoid any incorrect measurements, please ensure that the patient remains calm while the measurement is being taken. The patient may stand up or sit down.

Begin the measurement by pressing:

or

After a brief moment, the device will inflate the cuff. Once the required inflation pressure has been reached, the device will gradually decrease the pressure. Cuff pressures are displayed.

Once the measurement has been taken, the following information is displayed sequentially:

- systolic value (S/mmHg)
- diastolic value (D/mmHg)
- pulse rate (HR/min-1).

If an error message is displayed instead of the measurement value, e.g. ‚E 08' (insufficient recognition of oscillation), then attach the cuff more firmly and press the Start/Stop button again.

If the test measurement has been successful, then the device is ready for automatic measurement.

Instructing the patient

Explain to the patient how the device works (automatic blood pressure measurement at regular intervals) and make the following points:

- Stay calm during the measurement, so that there will be no incorrect readings as a result of any movement by the patient;
- During the night, it is best to place the PhysioQuant Recorder in its carrier bag on the bedside table;
- It is possible to manually switch between the day phase and the night phase;
- Record any unusual events in the patient diary and also carry out an additional measurement with the Start/Stop button if this happens;
- At any time, measurement can be interrupted via the Start/Stop button. Cuff pressure will then decrease;
- Do not open the battery compartment.

CAUTION

• Risk for patients •

Cancel the measurement with the Start/Stop button, if the cuff remains inflated for more than approx. 2 minutes

Take off the cuff if it remains inflated after pressing the Start/Stop button. It may be that the tube has been disconnected.

Further measurements should only be carried out after the cuff has been correctly attached again.

Important measurement information

For the first measurement, the device will inflate the cuff to approx. 160 mmHg (starting pressure). For subsequent measurements, the inflation pressure will be 25 mmHg above the last measured systolic value (minimum 120mmHg).

If the measurement value is in excess of the inflation pressure, then additional inflation of 50 mmHg will take place.

A manual measurement can be taken at any time between automatic measurements. This will be indicated by ‚+' in the measurement value table.

After an incorrect measurement, the measurement will be repeated after 2 minutes. An error message is only displayed in the error table with its corresponding error code after 3 incorrect measurements.

After the error messages ‚E04' (Empty battery/rechargeable battery), ‚E07' (Inflation time finished) and ‚E10' (200 measurements carried out), the measurement will not be repeated. After error message ‚E07', the subsequent measurement will again take place according to the selected measurement cycle.

After error messages ‚E04' and ‚E10' have been displayed, the device will switch to a power-saving mode, in order to avoid complete discharge of the rechargeable batteries. This mode can only be cancelled by switching the device on and off.

Key functions ergoscan

Ergoscan recorder buttons have the following functions during long-term blood pressure measurements:

is used too begin and end a measurement.

is used to display the most recent measured values or the most recent error message.

is used to manually switch the measurement intervals from the day to night phase, and vice versa.

Hint

Manually switch between day and night phase is possible, when 2 measurement intervals only have been programmed via the ErgoscanWin software when the starting sequence of the recorder was commenced and the keylock is not activated.

If more or less measurement intervals have been programmed, then the Day/Night button has no effect on the measurement intervals.

Key functions ergoscan duo

Ergoscan duo recorder buttons have the following functions during long-term blood pressure measurements:

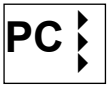
is used too begin and end a measurement.

pressed once is used to display the most recent measured values or the most recent error message.

pressed twice is used to manually switch the measurement intervals from the day to night phase, and vice versa.

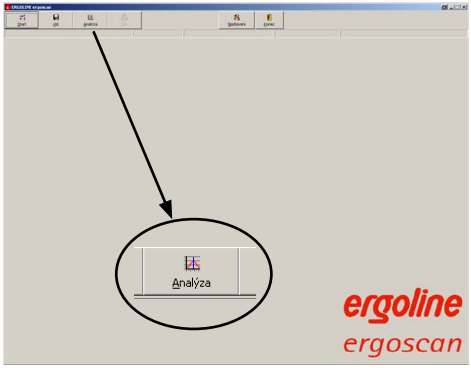
Reading measurement data from Recorder

- Connect the Ergoscan Recorder to the PC and switch on the recorder.
  The on/off switch is located beneath the lid of the battery compartment.
  Following self test and battery capacity the display shows the PC symbol:



Starting the Program

After the Ergoscan software has started, the main screen appears.
To read the data from the recorder, click on the ‚Import' tab.



Main screen: Import

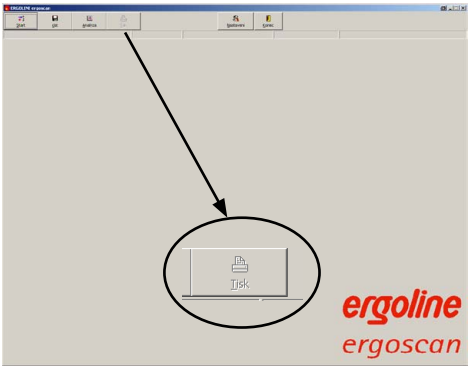
The measurement values are imported from the recorder and assigned to the relevant patient.

The graphical representation of the measurement results is also displayed

Analysis of measuremenet results

Start Program

After the ErgoScan software has started, the main screen appears.
To request saved measurement results, click on the [Analysis] tab to open the relevant screen:



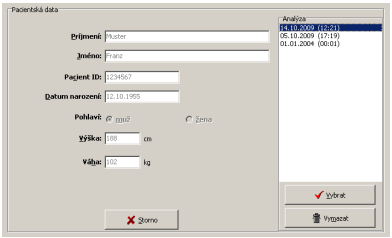
Main screen: Analysis

Find / Delete measurement results

The selection window of the patient database is displayed. Select the required patient.

The measurement result selection window appears for those patients whose data have been stored in the database.

You can request the relevant saved measurement results by double clicking on the relevant data in the selection window.



Selection mask for measurements

Deleting measurements
In order to delete a specific measurement result from the database, you need to click on the relevant date line in the selection window (the line will appear in blue). Then click on [Delete].

After a confirmation message appears, the result will be deleted..

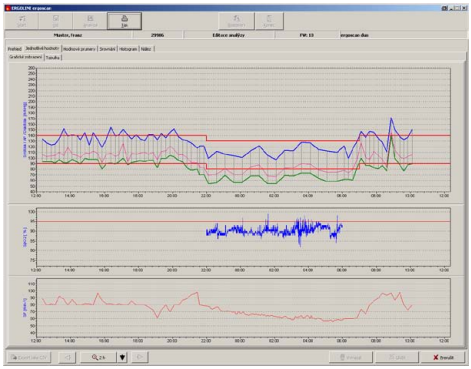
Representation

The saved measurement values can be represented in various ways, by clicking on the relevant tabs

Single values graph

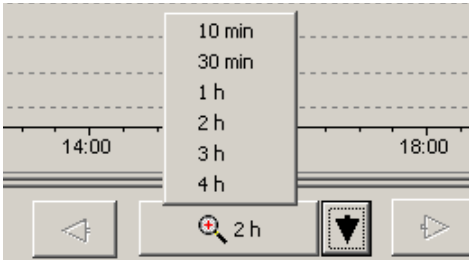
This graph displays the results of all individual measurements. The set critical values for the day and the night phase (see „Settings“) are displayed as red lines.

A ergoscan duo measurement additionally shows the grafic representation of the recorded SpO2 values.



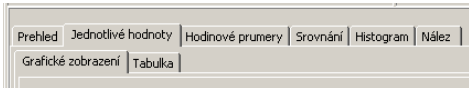
Single values graph

Zoom function
The integrated zoom function allows a more detailled view. The screen can be moved in adjustable steps (10min - 4h).
A click into the grafic activates the zoom - a second click returns to the complete display.



Zoom

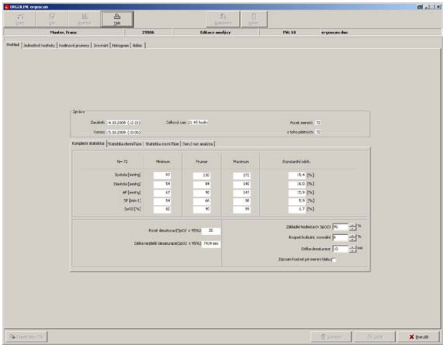
All other representations are displayed by clicking on the relevant tab.



Select representation

Overview / Statistics

The overview displays a numerical summary of the long-term blood pressure measurements, as well as the statistical measurement results, for the whole monitoring period, according to day and night phase.



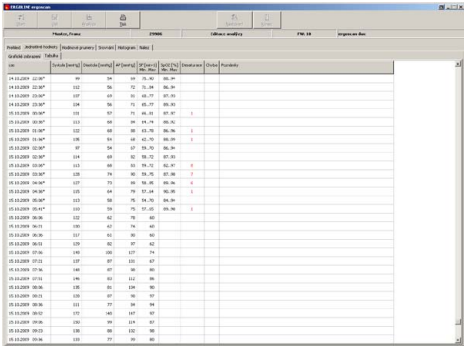
Overview / Statistics

Single values table

All measurement results are listed by date/time, systole, diastole, heart rate and mean pressure. Additional measurements (that have been carried out manually by using the Start/Stop button) are displayed behind the time indication and marked with the ‚+' symbol.

Deleting individual measurements

In order to delete individual measurements, you need to click on the relevant line (the line will appear in blue). Then click on [Delete]. After a confirmation message appears, the measurement will be deleted.



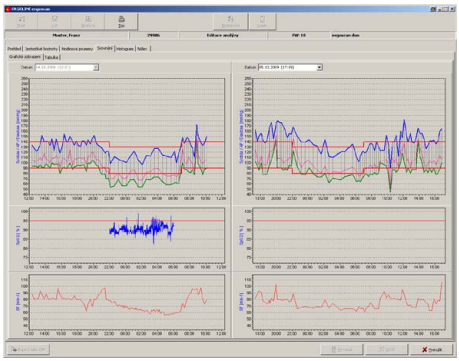
Single values table

Hourly mean values graph and table

In order to ensure a clear representation, only the calculated hourly mean values are displayed as a graph and a table.

Comparison graph and table

Two measurements of the same patient can be compared directly on the screen, either as a grafic or as a table.



Comparison of 2 measurements

Findings report

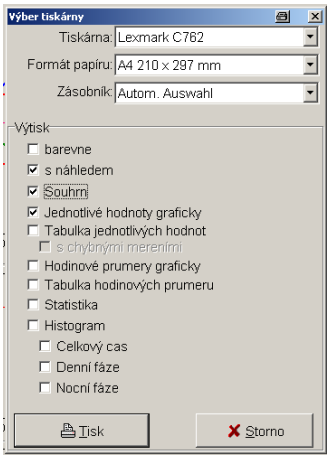
You can create a small report in relation to the findings of the long-term blood pressure measurements. This text will be summarised and can – when activated – also be forwarded to the general practice IT system..

Printing

You can print every page displaying measurement results by using the [Printing] button.

The size of the printout can be determined on an individual basis.
You can define a standard format under ‚Settings"

The integrated printing preview allows you to view the selected pages prior to printing.



SELECT PRINTOUT PAGES

PDF-Export

Die Schaltfläche [PDF-Export] erzeugt PDF-Dateien aus den Druckseiten – der Dateiname enthält alle Patienteninformationen.
Der Umfang der PDF-Dateien lässt sich jeweils individuell festlegen, ein Standardformat kann unter „Einstellungen" vordefiniert werden

GDT-Export to Patient File systems

If the GDT interface between ergoscan software and the general practice IT system interface has been activated, you can create a GDT export file in accordance with the selected settings by using the [GDT export] tab - the file will be saved in the configured directory.

CSV-Export

In representation [single values] [table] the button [CSV-Export] will generate a formatted textfile with all results.
This file is generated in the defined export folder (see „Settings"), the filename contains all necessary patient information.

Error Codes

E 03 Internal hardware error (contact the Service Department).

E 04 Batteries are empty. This is displayed as soon as the batteries have insufficient capacity to carry out measurements.

E 05 Measurement time has elapsed. This is displayed when measurement time (without inflation time) exceeds 60 seconds..

E 06 This error code will be displayed when:
- the actual cuff pressure exceeds the maximum allowable inflation pressure of 280 mmHg;
- the device is not inflating beyond the set maximum pressure and is waiting for the next measurement time.

E 07 The maximum inflation time of 60 seconds has elapsed.
Error refers to a loose cuff or tube, or another faulty sealing.

E 08 Insufficient oscillations have been detected:
At least 8 oscillations need to be detected for a correct measurement. The cuff should be attached sufficiently tightly (you should be able to put one finger beneath the cuff, but not two). Ergoscan will regulate the deflation rate for follow-up measurements accordingly.

E 10 Memory full. 200 blood pressure measurements have been carried out and the memory of the device is full.

E 11 Movement during diastole recognition.

E 12 Diastole is outside of the measurement range.

E 20 Systole is outside of the measurement range.
(E12 and E20 are displayed when the calculated systole or diastole values are outside the range in which the oscillations are recorded.)

E 21 Systole is below the measurement range.

E 22 Systole is above the measurement range

E 24 Difference between systole and diastole is too small (10 mmHg or less)

E 23 Movement during systole recognition.
Air deflation speed is too high, e.g. as a result of leakage.

Cleaning and Maintenance

Cleaning and disinfection of device surface

- Switch off the Ergoscan recorder
- Use only a moist cloth and ensure that no fluid enters the device. The most commonly used cleaning and disinfection agents in practices and clinics can be used.

CAUTION

• Danger of electric shock •

Always disconnect the device from your PC before cleaning it.

• Damage of device •

Do NOT use any disinfection agents that contain phenol and peroxide for disinfecting the surface of the device!

If any fluid has entered the device, then it should only be used again after having been checked and approved by the Service Department.

Cleaning and disinfection of cuffs

- Light stains can be removed by using a moist cloth.
- For heavier stains, rinse the cuff with soapsuds or disinfected cleaning agent (not in the washing machine!). No fluid should enter the cuff inflation section or the connecting tube (therefore please remove the inflation section when cleaning the cuff).
- After you have cleaned the cuff, you need to rinse it thoroughly with water and let it dry at room temperature for approx. 15 hours.
- You can also use any of the following to disinfect the device: isopropyl alcohol 70%, ethanol 70%, Microzid; Burazon liquid, Sporicidin or Cidex. After you have disinfected the cuff, rinse it thoroughly with water and leave it to dry at room temperature..

Cleaning and disinfection of SpO2 SoftTip sensors

Aids for cleaning / disinfection:

- Approved cleaning and disinfecting agent without protein-fixing effect (always observe the recommendations of the manufacturer when mixing).
- Compressed air
- Soft, disposable cloths
- Automated cleaning brushes
- Demineralised water

Commercially available cleaning and disinfecting agents approved for this purpose and based on aldehydes, alcohols, amines, bases or quaternary ammonium compounds are suitable for cleaning and disinfecting the SpO2 sensors as long as they exhibit similar active ingredient compositions and concentrations to the examples listed below.

Hint

The user must ensure that the process used to prepare the sensors for reuse is suitable for achieving the necessary results, including with regard to the suitability of resources, materials and personnel.

National standards and laws require compliance with validated preparation processes according to modern technological principles.

Productname	Manufacturer	use
Gigasept Instru AF (Glycoderivat)	Schülke & Mayr GmbH www.schuelke-mayr.com	Manual cleaning and disinfection
Gigasept FF (Aldehyd)		Manual cleaning and disinfection
Perfektan TB	Dr. Schumacher GmbH www.schumacher-online.com	Manual disinfection
Descoton forte (Aldehyd)		Manual disinfection
Neodisher LM2	Chem. Fabrik Dr. Weigert GmbH & Co. KG www.drweigert.de	Manual cleaning

Tested alkaline cleaning and disinfecting agents

Manuelle Reinigung, Desinfektion des SoftTip Sensors

1. The sensor must be carefully cleaned or disinfected after every use, and before use with a different patient.
   It is recommended that sensors be prepared for reuse immediately after use since dried residue can be difficult to remove. Avoid overfilling instrument sieves and wash trays.

3 Disconnect the sensor from the monitor before cleaning or disinfecting.

4. Thoroughly rinse the sensor to remove surface dirt

5. Clean all surfaces of the sensor (inside and outside) with a brush or disposable cloth and cleaning agent or disinfectant (observe manufacturer's instructions). We recommend turning the silicone housing of the sensor inside out for cleaning of the inside surfaces. The SoftTip sensors can be submersed in cleaning liquid (see Tab: List of approved cleaning agents).

6. Now rinse the sensor for at least 1 minute in approximately 200 ml of fully demineralised water. When doing so, the water must flow into the connector and the connector/socket holes must be repeatedly filled and emptied.

7 Ensure that all residue has been cleaned off the sensor.

8. If necessary, repeat the entire manual cleaning process.

9. A lint-free cloth can be used for manual drying, if necessary. Sensor cavities must be dried with sterile compressed air.

Safety information applicable standards

- *SoftTip sensors are NOT suitable for being autoclaved or machine cleaning.*
- *SpO2 sensors must not be cleaned in ultrasound baths. This process will destroy the sensors.*
- *Cleaners that react with silicone must not be used to prepare the sensors for reuse.*
- *Observe the instructions provided by the manufacturer for the cleaning and disinfecting device, the cleaning and disinfecting agents and the autoclave or steriliser.*
- *DIN EN ISO 17665-1 2006/11 – Sterilization of health care products.*
- *DIN EN 556-1 2002/03 – Sterilization of medical devices.*
- *Requirements for observing good hygiene practices and the respectively applicable procedures and rules.*

Inspection and function test

Visually inspect the sensors for damage.
Worn, deformed, porous or otherwise damaged sensors must not be reused.

Cleaning of cables

- Disconnect the cable from the device.
- Clean the cables with a moist cloth (soap-suds). NEVER dip the cables into any fluid.

Maintenance and validity check prior to any use

- Prior to using the device, manually check the device for any mechanical damage.
- If you notice any damage or functional errors, which may endanger the safety of the patient and user of the device, then you should only use the device again after it has been repaired.

Measurement technical check

The ergoscan is a measuring device in accordance with the German ‚Medical Device Code - Operation V' (‚MP Betrieb V') § 11/ Appendix 2.

As a result, the device must undergo a measurement technical check' every 2 years. The first of these checks should take place on the date indicated on the calibration mark.

Calibration mode

To check for example for any leakages in the pneumatic cycle, the ergoscan recorder can be switched into a calibration mode:

- Connect the pump ball over the T-piece between the supplying tube and cuff.
- Roll up the cuff tightly.
- Switch the device off and on.
- Wait until the display shows the time or a running bar (ergoscan duo).
- Press the INFO button 3 times: the display shows an internal value, which should be between 25 and 100.
  If the displayed value is outside this range, then the ergoscan Recorder must be sent in for maintenance.
- Press the Start/Stop button:
  The display shows ‚0' (current pressure in mmHg).
  Create a test pressure of 200 mmHg and measure the decrease in pressure after waiting a minimum of 30 seconds.
  (Decreases in pressure of 3...5 mmHg are normal. Decreases in pressure > 6 mmHg indicate the presence of an unacceptable leakage. In such an event, the ergoscan Recorder will need to be sent in for repair).
- You can exit the calibration mode by pressing the Start/Stop button.

Disposing of the device

At the end of its useful life, you need to dispose the device described in this manual, including all its accessories, in accordance with the disposal regulations for devices of this type.

If you have any questions in relation to disposal, then please contact egoline GmbH or one of its representatives.

TECHNICAL DATA

Bloodpressure measurement

Measurement

Measurement method	oscillometric
Measurement duration	30 – 45 sec. (depends on patient)
Data preservation	unlimited
Measurement intervals	2 – 90 min., programmable
Capacity	200 measurements or 30 hours

Measurement range

Systole	60 – 260 mmHg
Diastole	40 – 220 mmHg
Heartrate	35 – 240 beats/min

Cuff

Connection	Metal locking device
Size	available in different sizes
Cuff pressure	300 mmHg maximum, adjustable

SpO2 measurement (ergoscan duo only)

Measurement range

SpO2	45 - 100 %
Heartrate	20 – 300 beats/min

Accuracy

SpO2	+/- 2 % (70 - 100 %)
Heartrate	+/- 1 Digit (<= 100/min) +/- 1% (> 100/min)

Measurement method

SpO2	ChipOx ® technology (Split Pulse Wave with Fuzzy Logic Control)

Sampling rate

Interval	every 1, 2, 5 sec

SpO2 sensor

Connector	MiniMed connector
Sensor	Envitec SoftTip® sensor

Display / Operation controls

Patient display	LCD (measurement values, error codes)
Operation controls	Keypad (Start/Stop, Day/Night, Info)

Interface

PC connection	digital interface (USB)

Miscellaneous

Dimensions (L x W x H)	approx. 11 cm x 8.0 cm x 2.7 cm
Weight	190 g (incl. batteries)
Operating temperature	+10° to +40°
Rel. humidity	30 - 75 % (non-condensing)
Air pressure	700 - 1060 hPa
Power supply	2 NiMH rechargeable batteries (type Mignon AA, 1800 mAh) Alkaline batteries not recommended!

Battery Charger

Caution

Equipment damage, risk to patients —

- ***The charger is not a medical device. It must not be used in the patient environment.***
- ***The contact surface of the NiMH batteries and of the charger must always be kept clean.***
- ***The charger is to be used indoors only and must be protected against oil, grease, aggressive detergents and solvents to prevent damage.***
- ***If the charger is damaged in any way, e.g. after a drop or when the mains pins are bent, the local authorized dealer must be contacted immediately.***
- ***High temperatures affect the charging process. Ideally, the room temperature should not exceed 40 °C (104 °F).***
- ***After quick charging, please wait for some minutes before another quick charge. Otherwise the temperature sensors will not function correctly.***

If the recorder is powered by rechargeable batteries (4 of them are shipped with the equipment), they should be recharged immediately after use (24 hours). Use only the original charger supplied. It consists of an AC power adapter and the charging unit itself.

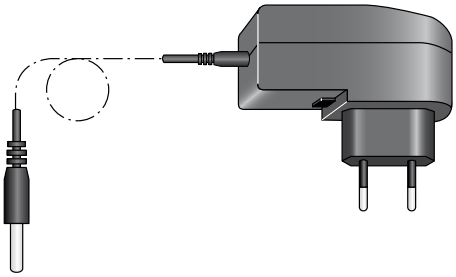


Fig. 1 AC power adapter

- Check that the voltage ratings on the nameplate of the charging unit match those of your local power line.
- Connect the cable of the AC power adapter to the charging unit and plug the AC power adapter into the wall outlet.

Charge Batteries with the VARTA Charger

Fig. 2 Battery symbols and bars in the charger display

Insert 4 or 2 batteries, observing their polarity. To charge only 2 batteries, insert them in the two compartments on the right or on the left. The batteries take up to 3 hours to recharge. Once the batteries are inserted, battery symbols will appear in the charger display where each symbol corresponds to one of the charger compartments (Fig. 2). During the charge cycle, the corresponding bar in the battery symbols blinks. Note: If the battery symbols and bar do not light up, only one battery may be inserted or the batteries are inserted the wrong way round. When the batteries are charged, the bars are permanently illuminated. The charging unit now trickle-charges the battery to compensate for self-discharging.

The battery temperature is monitored in the charger. When the temperature is too high, the bar in the battery symbol is permanently illuminated and the charger switches to trickle-charging.

If the batteries are correctly inserted and the displayed battery symbols show no bars, the charger has identified a battery problem. The charging current to the compartment concerned will be cut off. Remove the battery and discard, observing the applicable waste-disposal regulations.

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